



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Khan et al.

**Serial No.:** 09/716,777

**Filed:** November 20, 2000

**For:** IMMUNOREGULATOR

**Confirmation No.:** 9134

**Examiner:** J. Witz

**Group Art Unit:** 1651

**Attorney Docket No.:** 2183-4618US

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: EV325784470US

Date of Deposit with USPS: December 3, 2003

Person making Deposit: Christopher Haughton

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.

Serial No.: 09/716,777

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US- 4,977,244	12-11-1990	Muchmore et al.
US - 5,677,275	10-14-1997	Lunardi-Iskandar et al.
US - 5,877,148	03-02-1999	Lunardi-Iskandar et al.
US- 5,958,413	09-28-1999	Anagnostopoulos et al.
US - 5,968,513	10-19-1999	Gallo et al.
US - 5,997,871	12-07-1999	Gallo et al.
US - 6,319,504 B1	11-20-2001	Gallo et al.
US - 2003/0049273 A1	03-13-2003	Gallo et al.
US - 6,583,109 B1	06-24-2003	Gallo et al.
US - 6,596,688 B1	07-22-2003	Gallo et al.
US - 6,620,416 B1	09-16-2003	Gallo et al.
US- 2002/0064501	05-30-2002	Khan et al.
US- 2002/0041871	04-11-2002	Brudnak
US-5,851,997	12-22-1998	Harris
US- 6,489,296	12-03-2002	Grinnell et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
96/04008	02-15-1996	Government of the United States
97/49373	12-31-1997	University of Maryland Biotechnology Institute
97/49418	12-31-1997	University of Maryland Biotechnology Institute
97/49432	12-31-1997	University of Maryland Biotechnology Institute
WO 97/49721	12-31-1997	University of Maryland Biotechnology Institute
WO 01/010907 A3	02-15-2001	University of Maryland

Serial No.: 09/716,777

WO 01/11048 A2	02-15-2001	Biotechnology Institute University of Maryland Biotechnology Institute
EP 1 138 692 A1	10-04-2001	Erasmus Universiteit Rotterdam
EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam
WO 98/35691	08-20-1998	Proscript, Inc.
WO 99/59617	11-25-1999	Erasmus Universiteit Rotterdam
WO 01/10907	02-15-2001	University of Maryland Biotechnology Institute
WO 02/085117	10-31-2002	Eisai Co., Ltd.
DE 3715662	11-19-1987	The Wellcome Foundation Ltd.
DE 19953339	05-17-2001	Goldham Pharma GmbH

#### Other Documents

ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).

BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).

KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells in Vitro," 20(5-6) PLACENTA, page A37 (July 1999).

KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).

KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the  $\beta$ -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) HUMAN IMMUNOLOGY 1-7 (January 2002).

MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.

**Serial No.:** 09/716,777

MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.

PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).

SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin, "23(1) TRANSPLANTATION 103-104 (January 1977).

WULCZYN, F. Gregory, et al., "The NF-kB/Rel and Ikb gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).

YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2183-4799US  
Serial No.: 09/821,380  
Filing Date: 3/29/2001  
Title: IMMUNOREGULATOR

Attorney Docket No.: 2183-5223US  
Serial No.: 10/028,075  
Filing Date: 12/21/2001  
Title: GENE REGULATOR

Attorney Docket No.: 2183-5222US  
Serial No.: 10/029,206  
Filing Date: 12/21/2001  
Title: OLIGOPEPTIDE TREATMENT OF ANTHRAX

Attorney Docket No.: 3077-4618.1US  
Serial No.: 10/678,995  
Filing Date: 10/3/2003  
Title: IMMUNOREGULATOR

Serial No.: 09/716,777

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits subsequent to the filing of an RCE in the above-identified application.

Respectfully submitted,



Allen C. Turner

Registration No. 33,041

Attorney for Applicant(s)

TRASKBRITT, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

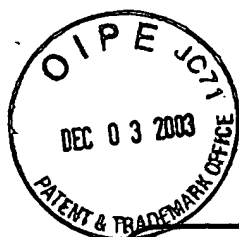
Date: November 26, 2003

ACT/bv

Enclosures: Form PTO-1449 or PTO/SB/08

Copy of documents cited

Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

Application Number	09/716,777
Filing Date	November 20, 2000
First Named Inventor	Khan et al.
Group Art Unit	1651
Examiner Name	J. Witz
Attorney Docket Number	2183-4618US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 4,977,244	12-11-1990	Muchmore et al.	
		US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		US- 5,968,513	10-19-1999	Gallo et al.	
		US- 5,997,871	12-07-1999	Gallo et al.	
		US- 6,319,504 B1	11-20-2001	Gallo et al.	
		US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		US- 6,583,109 B1	06-24-2003	Gallo et al.	
		US- 6,596,688 B1	07-22-2003	Gallo et al.	
		US- 6,620,416 B1	09-16-2003	Gallo et al.	
		US- 2002/0064501	05-30-2002	Khan et al.	
		US- 2002/0041871	04-11-2002	Brudnak	

**FOREIGN PATENT DOCUMENTS**

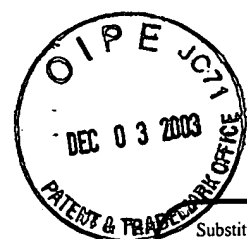
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		96/04008	02-15-1996	Government of the United States		
		97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		97/49432	12-31-1997	University of Maryland Biotechnology Institute		
		WO 97/49721	12-31-1997	University of Maryland Biotechnology Institute		
		WO 01/010907 A3	02-15-2001	University of Maryland Biotechnology Institute		
		WO 01/11048 A2	02-15-2001	University of Maryland Biotechnology Institute		
		EP 1 138 692 A1	10-04-2001	Erasmus Universiteit Rotterdam		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3

**Complete if Known**

Application Number	09/716,777
Filing Date	November 20, 2000
First Named Inventor	Khan et al.
Group Art Unit	1651
Examiner Name	J. Witz
Attorney Docket Number	2183-4618US

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>3</sup> (if known)			
		US-5,851,997	12-22-1998	Harris	
		US- 6,489,296	12-03-2002	Grinnell et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		WO 98/35691	08-20-1998	Proscript, Inc.		
		WO 99/59617	11-25-1999	Erasmus Universiteit Rotterdam		
		WO 01/10907	02-15-2001	University of Maryland Biotechnology Institute		
		WO 02/085117	10-31-2002	Eisai Co., Ltd.		
		DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
		DE 19953339	05-17-2001	Goldham Pharma GmbH		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

3

of

3

**Complete if Known**

Application Number	09/716,777
Filing Date	November 20, 2000
First Named Inventor	Khan et al.
Group Art Unit	1651
Examiner Name	J. Witz
Attorney Docket Number	2183-4618US

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	-
		BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
		KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells in Vitro," 20(5-6) PLACENTA, page A37 (July 1999).	-
		KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).	
		KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the $\beta$ -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) HUMAN IMMUNOLOGY 1-7 (January 2002).	
		MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	
		PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).	
		SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) TRANSPLANTATION 103-104 (January 1977).	
		WULCZYN, F. Gregory, et al., "The NF-kB/Rel and I $\kappa$ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).	
		YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.